DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Orthofix Srl
% Ms. Cheryl Wagoner
Principal Consultant
Wagoner Consulting LLC
PO Box 15729
Wilmington, North Carolina 28408

December 10, 2014

Re: K143125
Trade/Device Name: Orthofix TL-HEX True Lok Hexapod System (TL-HEX) V1.3
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation applications and accessories
Regulatory Class: Class II
Product Code: KTT, OSN
Dated: November 7, 2014
Received: November 10, 2014

Dear Ms. Wagoner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Special 510(k) Premarket Notification
Orthofix TL-HEX True Lok Hexapod System (TL-HEX) V1.3

Indications for Use

510(k) Number (if known): K143125

Device Name: Orthofix TL-HEX True Lok Hexapod System (TL-HEX) V1.3

Indications for Use:

The TL-HEX System is intended for limb lengthening by metaphyseal or epiphyseal distractions, fixation of open and closed fractures, treatment of non-union or pseudoarthrosis of long bones and correction of bony or soft tissue defects or deformities. Within this range, indications include:

- Post-traumatic joint contracture which has resulted in loss of range of motion
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
- Open and closed fracture fixation
- Pseudoarthrosis of long bones
- Limb lengthening by epiphyseal or metaphyseal distraction
- Correction of bony or soft tissue deformities
- Correction of bony or soft tissue defects
- Joint arthrodesis
- Infected fractures or non-unions

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

_____
(Division Sign Off)
Division of Orthopedic Devices
510(k) Number: K143125

Special 510(k) Premarket Notification
Orthofix TL-HEX True Lok Hexapod System (TL-HEX) V1.3

510(k) Summary
(as required by 21 CFR 807.92)

Submitter	Orthofix Srl
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Date Prepared	10/30/2014

Trade Name	Orthofix TL-HEX True Lok Hexapod System (TL-HEX) V1.3
Common Name	Multilateral Fixators and Accessories
Panel Code	Orthopaedics/87
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Class	Class II
Regulation Number	21 CFR 888.3030
Product Code	KTT, OSN

Name of Predicate Device	**510(k) #**	**Manufacturer**
Orthofix TL-HEX True Lok Hexapod System (TL-HEX)	K141078	Orthofix Srl

Description	The Subject device is a multilateral external fixation system. The System can also be used with a web-based software component that is designed to be used to assist the physician in creating a patient adjustment schedule that assists in adjusting the six struts. The System can also be used with other existing Orthofix external fixation components and screws (such as TrueLok or X Caliber). Components of the system include: • Full, 5/8 and 3/8 aluminum Rings • Double Row Footplates • Adjustable struts • Aluminum strut clips (number and direction) • Stainless steel instrumentation such as hex drivers, wrenches, and pliers • Implantable components such as half pins and wires • Web-based software

Indications and Intended Use	The TL-HEX System is intended for limb lengthening by metaphyseal or epiphyseal distractions, fixation of open and closed fractures, treatment of non-union or pseudoarthrosis of long bones and correction of bony or soft tissue defects or deformities. Within this range, indications include:

	• Post-traumatic joint contracture which has resulted in loss of range of motion • Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction • Open and closed fracture fixation • Pseudoarthrosis of long bones • Limb lengthening by epiphyseal or metaphyseal distraction • Correction of bony or soft tissue deformities • Correction of bony or soft tissue defects • Joint arthrodesis • Infected fractures or non-unions

Technological Characteristics and Substantial Equivalence	Documentation was provided to demonstrate that the subject device is substantially equivalent to the Predicate Orthofix TL-HEX True Lok Hexapod System (TL-HEX) (K141078). The subject device is substantially equivalent to the predicate device in intended use, indications for use, technological characteristics, and labeling. The subject device includes an extended range of rings, footplates, struts, and a consequent update of the software.

Performance Data	The potential hazards have been evaluated and controlled through a Risk Management Plan. All testing met or exceeded the requirements as established by the test protocols and applicable standards. A review of the mechanical data indicates that the hardware components of the Subject device are capable of withstanding expected loads without failure. Additionally, software verification and validation testing was completed in conformance with FDA's guidance document entitled "General Principles of Software Validation; Final Guidance for Industry and FDA Staff." The results of software testing indicate that the software performed as intended. The Subject device was therefore found to be substantially equivalent to the Predicate. Clinical data was not needed to support the safety and effectiveness of the Subject Device. The following mechanical and software testing were performed: • ASTM F 1541-02 (2007)e1 "Standard Specification and Test Methods for External Skeletal Fixation Devices" • Software IQ, OQ, PQ

Conclusion	Based on the indications for use, technological characteristics, materials, and comparison to predicate devices, the Subject Orthofix TL-HEX True Lok Hexapod System (TL_HEX) has been shown to be substantially equivalent to legally marketed predicate device, and is safe and effective for its intended use.